UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,654	01/27/2004	Suk H. Cho	09143-018002	1195

26191 7590 05/05/2006

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,654	CHO, SUK H.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24 and 26-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 26-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *4/17/2006*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of the receipt and entry of the amendment filed on February 2, 2006 with the cancellation of Claim 25 and the addition of newly submitted Claims 29-37.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 24 and 26-37 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 103

Claims 24 and 26, as amended, and newly added Claims 31, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guberman (AW), as evidenced by Guberman (V), in view of Mergens et al. (A). Newly applied as necessitated by amendment.

Applicant claims a method for reducing pain, inflammation, stiffness or discomfort in a mammal comprising administering a dietary supplement to the mammal in an amount effective to reduce pain, inflammation, stiffness or discomfort, wherein the dietary supplement comprises an aminosaccharide, a ginger component and an enzyme, wherein said aminosaccharide is granulated glucosamine or a granulated salt selected from the group consisting of glucosamine hydrochloride, glucosamine sulfate, glucosamine phosphate, glucosamine lactate, and glucosamine dodecanoate, wherein said dietary supplement is in the form of a tablet; and wherein about 40% to about 55%

of the tablet by weight is the aminosaccharide. Applicant further claims the method of claim 24, wherein the mammal receives a daily dose of the glucosamine, the daily dose being between 2 mg/kg and 20 mg/kg of body weight of the glucosamine;; wherein the enzyme is selected from the group consisting of bromelain, papain, fungal proteases, acid stable proteases, neutral stable proteases, and alkaline stable proteases; wherein daily administration of the dietary supplement to a mammal for at least two weeks reduces pain, stiffness, or inflammation in the mammal; and, wherein the tablet ranges from about 1000 mg to about 1500 mg.

The referenced product, 'Ultimate Joint Repair Formula', was found at http://thehealthstore.net/en-us/p_2.html. In an interview with Dr. Guberman on March 25, 2003, Guberman stated that he formulated the referenced product and that it has been in public use for four to five years for use by humans. The 'Ultimate Joint Repair Formula' taught by Guberman comprises 1500 mg of glucosamine sulfate and 420 mg of a proprietary blend of the following ingredients: bromelain (80+ GDU); *Boswellia serrata* extract (40%); tumeric and ginger. Guberman further taught that the referenced product is used in the treatment of arthritic conditions for pain, inflammation and joint repair. Guberman teaches, "In severe joint repair situations: Start with three capsules taken three times per day for one month, then taper off and seek level at which you feel continued relief."

In another interview, as set forth in "*Examiner-Initiated Interview Summary*" (PTOL-413B (04-03)) and dated April 17, 2006, Dr. Guberman stated he was the developer of "Ultimate Joint Repair Formula" which comprises glucosamine sulfate,

chondroitin sulfate, methylsulfonylmethane, essential fatty acid complex, manganese and a proprietary blend of ingredients as described at http://www.thehealthstore.net/en-us/p_2.html (downloaded 3/24/2003). Dr. Guberman also stated that the referenced formula has been sold in the United States and in public use in the United States since 1999 for treatment of arthritic conditions pain, inflammation and joint repair. As proof that the referenced composition has been in public use and on sale in the United States for repairing damaged joints or treating arthritis, etc., Dr. Guberman fascimiled a copy of an invoice statement for the sale of the "Ultimate Joint Repair Formula" bearing the date 12/12/2000.

The teachings of Guberman are set forth above. It is not clear from the teachings of Guberman (AW) whether the glucosamine contained therein the referenced product and method of use thereof is in the form of a granulated glucosamine. Therefore, Guberman teaches the instantly claimed method of treatment except for wherein the aminosaccharide is granulated glucosamine or a granulated salt selected from the group consisting of glucosamine hydrochloride, glucosamine sulfate, glucosamine phosphate, glucosamine lactate, and glucosamine dodecanoate. However, (in the event that the glucosamine comprising the composition taught by Guberman is not granulated) it would have been obvious to one of ordinary skill in the art to replace the glucosamine used in the making of the composition taught by Guberman with a granulated glucosamine or a granulated salt selected from the group consisting of glucosamine hydrochloride, glucosamine sulfate, glucosamine phosphate, glucosamine lactate, and glucosamine dodecanoate to provide the instantly claimed

method of treatment because at the time the invention was made Mergens taught a process of making a tablet and a tablet thereof comprising a granulated aminosaccharide (such as glucosamine hydrochloride or glucosamine sulfate or N-acetyl glucosamine sulfate), chondroitin, anti-inflammatory agents, as well as, herbal-based therapeutic agents or extracts. In Column 13, lines 39-41, Mergens taught, "The overall weight of the tablet ranges from about 100 mg to about 2000 mg, and more preferably from about 450 mg to about 1600 mg." At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to replace the glucosamine used in the making of the "Ultimate Joint Repair Formulation" taught by Guberman to with a granulated glucosamine or a granulated salt selected from the group consisting of glucosamine hydrochloride, glucosamine sulfate, glucosamine phosphate, glucosamine lactate, and glucosamine dodecanoate to provide the instantly claimed invention because at the time the invention was made Mergens taught that "the tablets may be formulated to provide treatment of connective tissue, such as to prevent, repair, or lessen ailments of the joints and cartilage tissue, such as observed with arthritis", in Column 13, lines 43-48; and, in Column 13, line 61 to Column 14, line 10, the Mergens' tablet compositions were taught to have the following advantages: "For example, by the tablet compositions being substantially free of excipients, smaller (in weight and volume) tablets can be prepared containing the same amount of therapeutic compound. By decreasing the excipients present in the tablet, the tablets prepared according to the method of the present invention can be more easily ingested, and/or formulated to contain more

therapeutic compound(s) in a single tablet. By being able to increase the amount of therapeutic compounds in a single tablet, one reduces the need to ingest multiple tablets at a single time and/or multiple doses of the same product. Additionally, the reduction of excipients in tablets is beneficial to hyper-allergenic patients and also has a very positive effect on diurnal consumer compliance."

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 24 and 26, as amended, Claims 27 and 28 and newly added Claims 30, 31, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Guberman (AW and V) and Mergens et al. (A*) in view of and Sharma et al. (U). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 24, 26, 31, 36 and 37 was set forth above. Applicant further claims the method of claim 24, wherein the ginger component is ginger oil; and, wherein about 5% to about 15% of the tablet by weight is the ginger component. Applicant further claims the method of claim 27, wherein the mammal receives a daily dose of the ginger oil, the daily dose being 25 mg/kg and 50 mg/kg of body weight of the ginger oil.

The combined teachings of Guberman (AW and V) and Mergens are set forth above. The combined teachings of Guberman and Mergens teach the instantly claimed invention except for ginger oil. However, it would have been obvious to one of ordinary

skill in the art to add an effective amount of ginger oil to the method taught by the combined teachings of Guberman and Mergens to provide the instantly claimed method of treatment because at the time the invention was made Sharma taught a method comprising the administration of effective amounts of ginger oil that was beneficial in the treatment of inflammatory disease conditions. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add ginger oil to the method taught by the combined teachings of Guberman and Mergens to provide the instantly claimed method of treatment because Sharma taught that the administration of effective amounts of ginger oil to a mammal provide potent anti-inflammatory and/or anti-rheumatic activity.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add ginger oil in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the ginger oil taught by Sharma to the method taught by the combined teachings of Guberman and Mergens to provide the claimed

method because the claimed invention is no more than the combining of well known ingredients used in well known methods for reducing pain, inflammation, stiffness or discomfort in a mammal.

As each of the references indicate that the various proportions and amounts of the ingredients used in the dietary supplement, which is in the form of a tablet, or the claimed dietary supplement combination(s) are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 24 and 26, as amended, and newly added Claims 29-31, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guberman (AW and V) and Mergens et al. (A) in view of Rose et al. (AT, 6,344,220). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 24, 26, 30, 31, 36 and 37 was set forth above. Applicant further claims the method of claim 24, wherein the ginger component is gingerroot or gingerroot extract.

The combined teachings of Guberman (AW and V) and Mergens are set forth above. The combined teachings of Guberman and Mergens teach the instantly claimed invention except for wherein the ginger component is either gingerroot or gingerroot

extract. However, it would have been obvious to one of ordinary skill in the art to add an effective amount of either gingerroot or gingerroot extract to the method taught by the combined teachings of Guberman and Mergens to provide the instantly claimed method of treatment because at the time the invention was made Rose taught a composition and a method of use thereof wherein the composition when administered to an animal arrests the inflammatory response in affected tissues and facilitates the repair and maintenance of damaged tissues in the joints of vertebrates. The composition taught by Rose comprises glucosamine and its salts in an amount of 50 mg to about 2000 mg per 25 pounds of body weight (*see* Column 5, lines 5-18 and lines 23-27; and ginger or gingerroot in an amount of 50 mg to about 220 mg per 25 pounds of body weight (*see* Column 6, lines 24-28). At the time the invention was made, one of ordinary skill in the art would have had a reasonable expectation of success to add and/or substitute the gingerroot taught by Rose to the composition used in the method of treatment taught by the combined teachings of Guberman and Mergens to provide the instantly claimed invention because Rose teaches, in Column 6, lines 6-11, that gingerroot "functions as a circulatory stimulant to relax peripheral blood vessels thus serving the dual beneficial roles of removing detrimental inflammatory by-products such as free radicals and transporting an ample supply of antioxidants and metabolic precursor building blocks of repair."

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or

more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add either gingerroot or gingerroot extract to the dietary supplement used in the method taught by the combined teachings of Guberman and Mergens to provide the claimed invention because Rose taught the beneficial functional effects of the claim-designated ginger components.

It also would have been obvious to one of ordinary skill in the art to optimize the amounts of the ginger component comprising the dietary supplement used in the method taught by the combined teachings of Guberman and Mergens to provide the instantly claimed method of treatment because at the time the invention was made ginger components, such as gingerroot or gingerroot extract or ginger, were known to have beneficial functional effects, as evidenced by the teachings of Rose as set forth immediately above. At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of success to add a ginger component, such as the instantly claimed ginger, gingerroot or gingerroot extract, in the amounts instantly claimed and to

adjust the amount of the ginger component comprising the combined teachings of the aforementioned references to provide the claimed invention because Rose teaches, in Column 6, lines 24-28, "the phytochemical included in a composition for treating joint disorders is ginger or ginger root, the daily dose for vertebrates is preferably from about 50 to about 220 mg of ginger or ginger root per 25 pounds of body weight." Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the amounts of the ingredients used in the making of the claim-designated composition for use in the instantly claimed method of treatment because it would have been well in the purview of one of ordinary skill in the art practicing the invention to select result-effect amounts of the claimed ingredients to provide a composition with the claimed functional effect for reducing pain, stiffness, inflammation or discomfort in a mammal via oral administration. Hence, the claimed invention is no more than the routine optimization of a result effect variable.

As each of the references indicate that the various proportions and amounts of the ingredients used in the dietary supplement, which is in the form of a tablet, or the claimed dietary supplement combination(s) are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 24 and 26, as amended, and newly added Claims 31-33 and 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guberman (AW and V) and Mergens et al. (A) in view of Balch et al. (ABB), American Biologics (AY) and Wood et al. (ABBB). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 24, 26, 31, 36 and 37 was set forth above. Applicant further claims the method of claim 24, wherein about 1% to about 10% of the tablet is the enzyme; and, wherein the dietary supplement comprises at least two different enzymes.

The combined teachings of Guberman and Mergens are set forth above. The combined teachings of Guberman and Mergens teach the instantly claimed method except for wherein about 1% to about 10% of the tablet is the enzyme; and, wherein the dietary supplement comprises at least two different enzymes. However, it would have been obvious to one of ordinary skill in the art to modify the dietary supplement used in the method of treatment taught by the combined teachings of Guberman and Mergens wherein about 1% to about 10% of the tablet is the enzyme; and, wherein the dietary supplement comprises at least two different enzymes to provide the instantly claimed invention because at the time the invention was made it was known in the art the beneficial functional effect that multiple enzymes in the claimed amounts have in the making of a dietary supplement, as evidenced by the teachings of Balch, and as further evidenced by the teachings of American Biologics, Maryln Nutraceuticals and Wood. For instance, on page 48, Column 2, lines 29-45, Balch teaches compositions comprising a combination of enzymes. Firstly, Balch teaches INFLAZYME FORTE™

from American Biologics, which is a formula of "a combination of enzymes and antioxidants for people requiring supplemental digestive enzymes to aid in the breakdown of proteins, fats, and carbohydrates. It may also be helpful for chronic or acute inflammation." As evidenced by the teachings of American Biologics, INFLAZYME FORTE™ comprises pancreatin (800 mg), bromelain (125 mg), papain (120 mg), trypsin (120 mg), chymotrypsin (2.5 mg), lipase (35 mg), rutin (flavonoid), zinc, superoxidase dismutase (100 units), catalase (50 IU), and cysteine. INFLAZYME FORTE™ is taught as a combination of digestive and anti-inflammatory, with antioxidants and metabolic cofactors: "The enzymes in INFLAZYME FORTE™ help degrade and otherwise disarm macromolecular components of the inflammatory cascades, while the antioxidants and cofactors help dampen the free radicals produced during the course of acute or chronic inflammation." American Biologics suggests an intake of three to six tablets, three times per day for the referenced dietary supplement. Secondly, Balch teaches Wobenzym N from Marlyn Nutraceuticals, which is a combination of enzymes. As evidenced by the teachings of Marlyn Nutraceuticals, Inc., Wobenzym N comprises pancreatin (100 mg), trypsin (24 mg), chymotrypsin (1 mg), bromelain (45 mg), papain (60 mg), and rutosid. As evidenced by the teachings of Wood, the combination of the enzymes comprising Wobenzym N show sequential synergy in inflammatory processes. Marlyn Nutraceuticals suggests three tablets of the referenced dietary supplement, two to three times daily, 45 minutes before meals. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the

multiple enzyme formulations taught by Balch, and as evidenced by the teachings of American Biologics, Marlyn Nutraceuticals and Wood, to the composition taught by the combined teachings of Guberman and Mergens, and to optimize the percentage amounts of the enzymes contained therein the resulting dietary supplement to provide the claimed invention because Balch, American Biologics, Marlyn Nutraceuticals and Wood each taught the beneficial anti-inflammatory effects that their multiple enzyme containing products exert in mammals, when they are administered within the dosage range as instantly claimed by Applicant.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredients in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the dietary supplement, which is in the form of a tablet, or the claimed dietary supplement combination(s) are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 24 and 26, as amended, and newly added Claims 31, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guberman (AW and V) and Mergens et al. (A) in view of Haqqi et al. (ASS) and Bailey et al. (AS, US 6,210,679). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 24, 26, 31, 36 and 37 was set forth above. Applicant further claims the method of claim 24, wherein the dietary supplement comprises a green tea extract. Applicant further claims the method of claim 34, wherein about 1% to about 10% of the tablet by weight is the green tea extract.

The combined teachings of Guberman and Mergens are set forth above. The combined teachings of Guberman and Mergens teach the instantly claimed invention except for wherein the dietary supplement comprises a green tea extract; and, except for wherein about 1% to about 10% of the tablet by weight is the green tea extract. However, it would have been obvious to one of ordinary skill in the art to add green tea to the dietary supplement used in the method taught by the aforementioned combined teachings to provide a dietary supplementary wherein about 1% to about 10% of the tablet by weight is the green tea extract because at the time the invention was made Haqqi and Bailey taught the beneficial functional effects of green tea extract. Firstly, Haqqi taught a method of administering an antioxidant-rich solution of 0.2%

polyphenolic fraction (GTP) extracted from green tea to mice. Haqqi taught that the oral administration of GTP reduced the expression of inflammatory mediators such as cyclooxygenase 2, IFN-Y, and tumor necrosis factor a in arthritic joints of GTP-fed mice. Secondly, Bailey taught isolating caffeine-free catechins and caffeine-free EGCF from green tea leaves, which are useful in formulating therapeutic pharmaceutical and nutraceutical products. In Column 1, lines 9-22, Bailey teaches, "Green tea catechins have been shown to not only prevent against lipid peroxidation but also scavenge both oxygen and hydroxide radicals"; and suggests that the anti-oxidative properties of green tea extract is useful in the treatment of degenerative diseases, such as arthritis. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the green tea extract to the compositions used in the method taught by the combined teachings of Guberman and Mergens and to optimize the amounts of the claimed green tea extract to provide the claim-designated supplement because Haqqi suggested that green tea and its polyphenols may prove to be a useful supplement/addition with other agents for the treatment of arthritis and other autoimmune diseases, on page 4529, Column 1, lines 39-44; and, Bailey suggested that the highly purified caffeine-free green tea catechins of his invention are useful in the making of pharmaceutical and nutraceutical products and provide a natural source of antioxidants, in Column 1 bridging Column 2, lines 1-37. Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the amounts of the ingredients used in the claim-designated dietary supplement because it would have

been well in the purview of one of ordinary skill in the art practicing the instantly claimed method of treatment to select result-effect amounts of the claimed ingredients to provide a composition with the claimed functional effect to reduce to reduce pain, stiffness, inflammation or discomfort in a mammal. Hence, the claimed invention is no more than the routine optimization of a result effect variable.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredient in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the dietary supplement, which is in the form of a tablet, or the claimed dietary supplement combination(s) are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
April 27, 2006